NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RECKITT BENCKISER INC. et al.,	:	**Civil Action No.: 09-3125 (FLW)**
Plaintiffs,	:	
v.	:	**MEMORANDUM OPINION AND ORDER**
TRIS PHARMA, INC., et al.,	:	
Defendants.	:	

ARPERT, U.S.M.J

This matter having come before the Court on the informal application of Plaintiffs Reckitt Benckiser Inc. and UCB Manufacturing, Inc. (collectively, "Plaintiffs"), by letter to the Court dated June 14, 2011, renewing their request to compel production of all documents responsive to Plaintiffs' document request nos. 3-6, 8-15, 17-22, 27-33, 35, 36, 43, 44, 53-58, 62, 63, and 65 regarding "platform technologies", not merely those documents specifically related to dextromethorphan. The Court notes that during the May 17, 2011 telephone status conference, Defendants identified Dr. Tu as the person most knowledgeable with respect to Tris' "platform technologies" and Plaintiffs were granted permission to depose Yu-Hsing Tu ("Dr. Tu") in order to determine if the information requested related to "platform technologies" was relevant for purposes of this litigation. Defendants Tris Pharma, Inc. ("Tris") and Dr. Tu (collectively, "Defendants") filed opposition to Plaintiffs' renewed request in a letter to the Court dated June 27, 2011. Plaintiffs filed a supplemental letter brief in support of their application on July 14, 2011. Defendants filed supplemental opposition in a letter to the Court dated July 18, 2011. The Court conducted oral argument, by telephone, on September 22, 2011. For the reasons stated on the record and herein, Plaintiffs' application to compel is denied.

In sum, Plaintiffs – as the holder of an approved new drug application ("NDA") no. 18-658 for Delsym extended release liquid suspension which contains the active ingredient dextromethorphan polistirex ("dextromethorphan") – filed a Complaint against Tris on June 26, 2009 alleging infringement of United States Letters Patent No. 5,980,882 ("'882 patent") which "claims certain pharmaceutical compositions using a drug-resin complex and a chelating agent and certain methods of making these pharmaceutical compositions". *See* Pl.'s Compl., dkt. entry no. 1 at 1-3. Plaintiffs allege that by submitting an abbreviated new drug application ("ANDA") under the provisions of 21 U.S.C. § 355 (j) before the expiration of the '882 patent – specifically, seeking approval to engage in the commercial manufacture, use, and sale of dextromethorphan polistirex extended release suspension – Tris committed an act of infringement under 35 U.S.C. § 271(e)(2) and will also infringe one or more claims of the '882 patent. *Id*. at 4. As a result, Plaintiffs claim that they are entitled to a Court Order stating that the effective date of any approval of Tris' ANDA be no earlier than after the expiration date of the '882 patent pursuant to 35 U.S.C. § 271(e)(4) and an award of damages for any commercial sale or use by Tris with respect to the subject matter claimed in the '882 patent. *Id*. at 5. Plaintiffs also claim that they are entitled to reasonable attorneys' fees, judgment that Tris infringed one or more claims of the '882 patent, and a permanent injunction against Tris from engaging in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of Tris' product. *Id*. at 5-7. On June 11, 2010, Plaintiffs filed an Amended Complaint adding Dr. Tu as a defendant and adding additional counts of trade secret misappropriation, unfair competition, breach of contract, and tortious interference with business expectations. *See* Pl.'s Amended Compl., dkt. entry no. 51 at 1-15. On February 28, 2011, the Court dismissed Count IV (breach of contract) of Plaintiffs' Amended Complaint without prejudice based on

Plaintiffs' failure to identify any specific contract or contracts that governed Dr. Tu's employment and failure to identify or describe any of the provisions or terms of the agreement relevant to this dispute. *See* dkt. entry nos. 79-80.

With this informal application, Plaintiffs renew their assertion that "Tris' internal documents and press releases" – which "identify...specific 'platform technologies' as key to Tris' infringing dextromethorphan resins complexes" – demonstrate that discovery related to "Tris' 'platform technologies'" is "highly relevant to this litigation" and should be produced. *See* Pl.'s Letter dated June 14, 2011 at 1-3. Plaintiffs note that the "Court has ruled that the asserted claims for the patent in suit recite processes for treating compositions using [the] chelating agent EDTA regardless as to when added or if EDTA is removed" and that because "Tris began working on its ANDA product on about July 2002...and finalized its ANDA product on about July 2008", "Tris' process for making its generic dextromethorphan resin ANDA product incorporates Tris' 'platform technologies' and includes a step where its resin is treated with EDTA". *Id*. at 2. Plaintiffs contend that "Dr. Tu's deposition confirmed...[that] the 'platform technologies' work involving other ingredients was intertwined with work on Tris' infringing dextromethorphan product" and that "review of the documents relating to that work is necessary to determine what work was actually performed, when, and by whom" because although "Dr. Tu was unable to provide...basic information", "he conceded that [such] information could be readily determined based on documents Tris has been withholding". *Id*. at 1-2. Specifically, Plaintiffs note that Dr. Tu confirmed that the "'platform technologies'...[were] treated with the chelating agent EDTA prior to forming a drug-resin complex...just as with...dextromethorphan", that "his 2007 patent application...encompasses aspects of the OralXR+ and LiquiXR platforms...and list[ed] examples involving 14 different active ingredients", that "work involving

each of these active ingredients combined with the 'platform technology' contributed to the development of the subject matter of the patent application...[and] also includes examples of using the 'platform technologies' with dextromethorphan", that "[his] failed efforts...[with other active ingredients that were incompatible with the 'platform technologies'] contributed to the development of these technologies", that "work with the 'platform technologies' without any active ingredients contributed to his 2007 patent application...as well as the development of...dextromethorphan", and that "Tris' dextromethrophan work overlapped with...his work on a hydrocodone resin product". *Id.* at 3-4. Plaintiffs contend that despite Defendants' representation that Dr. Tu "was the most knowledgeable researcher regarding Tris' OralXR+ and LiquiXR technologies", "Dr. Tu showed a significant lack of knowledge regarding those key technologies", "repeatedly denied even understanding what these terms meant", was "unable to identify any individual at Tris who...worked on the development of OralXR+ or LiquiXR", and "did not know when Tris conducted the work underlying nearly all of the examples in the...[2007 patent] application". *Id.* at 4-5. Further, Plaintiffs maintain that Dr. Tu's "self-serving statements" in response "to his own counsel's questions" are "contradicted by [his] professed wholesale lack of knowledge regarding the 'platform technologies'". *Id.* Separately, Plaintiffs maintain that, based upon "objective evidence" – "multiple presentations to prospective business partners" and "a patent application filed in March 2007" – "it is clear that work relating to Tris' 'platform technologies' was not conducted in isolation for dextromethorphan alone, but was done in connection with other active ingredients and products" and therefore "the documents withheld by Defendants relating to the 'platform technologies' are relevant to this case and must be produced". *Id.* at 2-3. In addition, Plaintiffs maintain that the deposition testimony of Peter Ciano, Ashok Permual, and Zhisong Liu, and the additional deposition testimony provided by Dr.

Tu, demonstrate that "Oral XR+ and LiquiXR use the same EDTA, the same resin, the same EDTA treatment process, the same polymer coating, and potentially the same suspension as Tris' ANDA product" and confirm that an intertwined development process occurred. *See* Pl.'s Suppl. Letter dated July 14, 2011 at 1-3. Plaintiffs argue that "Defendants [have] failed to establish that the 'platform technologies' used for Tris'...dextromethorphan...was developed with and for that product alone", that "Plaintiffs have met their burden", and that discovery related to "platform technologies" should be compelled. *See* Pl.'s Letter dated June 14, 2011 at 5-6.

In opposition, Defendants initially note that "[t]he only accused product" in this litigation "is the subject of Tris' ANDA" – "an extended release dextromethorphan suspension generic to Delsym" – and that "[n]o other 'LiquiXR' or 'OralXR+' product has been accused of infringement...nor are these so-called 'platform technologies' at issue in a general sense". *See* Def.'s Opp'n Letter dated June 27, 2011 at 5-6. Defendants also note that "Plaintiffs' [original] argument for discovery rested on a few Tris slide presentations that were nontechnical and intended to provide an overview of the company's capabilities to potential customers" and which "used the coined terms 'LiquiXR' and 'OralXR+' for the broad categories of liquid extended-release products and oral extended-release products, respectively". *Id*. at 1-2. Defendants contend that these terms "do not designate specific formulation techniques or products" and are in fact "business terms". *Id*. at 2, 5. Citing portions of Dr. Tu's deposition testimony, Defendants maintain that "development work on the generic dextromethorphan extended release suspension" did not "incorporate the results of research on any other actives" because "[d]extromethorphan was developed...before...other active pharmaceutical ingredients ("API")". *Id*. at 2-4. Citing other portions of Dr. Tu's deposition testimony, Defendants argue that "Plaintiffs' claim that work involving other ingredients was intertwined with the work of Tris'

infringing dextromethorphan product is factually unsound and highly misleading" because "dextromethorphan was the 'first' and 'model' API used in developing [Tris'] drug-resin products" due, at least in part, to the fact that "dextromethorphan...is a non-controlled substance". *Id*. at 5-6. Although Plaintiffs claim that a certain business presentation and a certain patent application are "objective evidence that make clear that work relating to Tris' 'platform technologies' was not conducted in isolation for dextromethorphan alone but was done in connection with other active ingredients and products", Defendants contend that, "[a]t best, these documents show that [Tris] was working on more than one drug-resin product at the same time". *Id*. at 7. Defendants argue that "[n]othing in these documents contradict[s] Dr. Tu's testimony that work conducted on other active ingredients was conducted later than work on dextromethorphan" or "that work on these other actives did not inform the development of the accused dextromethorphan product" and that, in fact, these documents "confirm that Tris...has complied with its discovery obligations". *Id*. at 7-8. Similarly, with respect to the other deposition testimony referred to by Plaintiffs in their supplemental letter, Defendants maintain that same "shows only that the development of the accused product overlapped in time with [the] development of other products that are not accused of infringement" and that "[t]his overlap is insufficent to show that development documents for other products are germane to any issue in this case". *See* Def.'s Suppl. Opp'n Letter dated July 18, 2011 at 1-2.

The Court notes that pursuant to FED. R. CIV. P. 26(b)(1), "parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense...including the existence, description, nature, custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter" and "the court may order discovery of any matter relevant to the subject matter involved in the

action", although "relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence". Importantly, "[t]he party resisting discovery has the burden of clarifying and explaining its objections and to provide support therefor". *See Tele-Radio Systems, Ltd. v. De Forest Electronics, Inc.*, 92 F.R.D. 371, 375 (D.N.J. 1981); *see also Gulf Oil Corp. v. Schlesinger*, 465 F. Supp. 913, 916-17 (E.D. Pa. 1979); *Robinson v. Magovern*, 83 F.R.D. 79, 85 (E.D. Pa. 1979).

Initially, the Court notes that the only product at issue in this litigation is Defendants' "dextromethorphan polistirex extended release suspension". *See* Pl.'s Compl. at 4-5; *see also* Pl.'s Amended Compl. at 4-5. The Court finds that Plaintiffs have failed to meet their burden with respect to demonstrating why the requested discovery is relevant and Defendants have sustained their objections. Specifically, Dr. Tu testified that dextromethorphan extended release suspension did not incorporate the results of research on any other API (*see* Def.'s Opp'n Br. at Ex A – Dr. Tu Tr. 204:20-25), that dextromethorphan was developed first and before any other API (*Id*. at Ex. A – Dr. Tu Tr. 205:1-8), that development of the drug resin complex formation was done first with dextromethorphan (*Id*. at Ex. A – Dr. Tu Tr. 206:1 thru 207:9), that development of the precoating treatment was done first with dextromethorphan (*Id*. at Ex. A – Dr. Tu Tr. 207:10-15), that development of particle coating and curing was done first with dextromethorphan (*Id*. at Ex. A – Dr. Tu Tr. 207:16-23), that suspension, manufacturing, and packaging were done first with dextromethorphan (*Id*. at Ex. A – Dr. Tu Tr. 207-24 thru 208-3), and that none of the development steps of dextromethorphan incorporated any information from development work on any other API (*Id*. at Ex. A – Dr. Tu Tr. 208:4-9). Dr. Tu also testified that the flavor of dextromethorphan was not based on work with any other API (*Id*. at Ex. A – Dr. Tu Tr. 208:10-23), that the choice of vendor and flavoring agent for dextromethorphan was

not based on any other API (*Id*. at Ex. A – Dr. Tu Tr. 208:24 thru 209:4), that neither the suspending agents nor the amounts or ratios used in dextromethorphan were selected based on work done on any other API (*Id*. at Ex. A – Dr. Tu Tr. 209:14 thrugh 210:4), and that the recipe for dextromethorphan was not based on work with any other API (*Id*. at Ex. A – Dr. Tu Tr. 210:5-20). Finally, Dr. Tu testified that the only API used in developing the subject matter of the patent at issue was dextromethorphan (*Id*. at Ex. A – Dr. Tu Tr. 147:9-15) and that research for the 14 examples in the patent at issue were not done at the same time because dextromethorphan was developed first and used as model (*Id*. at Ex. A – Dr. Tu Tr. 169:12 thru 170:20). Even if development of the accused product overlapped in time with the development of other products that are not accused of infringement (*e.g.*, the "platform technologies"), the Court finds that this overlap is insufficient to show that development documents for other products are germane to any issue in this case.

Having considered the papers submitted and the opposition thereto, and having conducted oral argument on September 22, 2011, and for the reasons stated on the record and set forth above;

IT IS on this 17th day of October, 2011,

ORDERED that Plaintiffs' informal application to compel production of all documents responsive to Plaintiffs' document requests nos. 3-6, 8-15, 17-22, 27-33, 35, 36, 43, 44, 53-58, 62, 63, and 65 regarding "platform technologies" is **DENIED**.

s/ *Douglas E. Arpert*
DOUGLAS E. ARPERT
UNITED STATES MAGISTRATE JUDGE